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10/585,705	07/08/2006	Scheffer C.G. Tseng	34157-709.831	4355
21971 7590 12/17/2009 WILSON, SONSINI, GOODRICH & ROSATI 650 PAGE MILL ROAD PALO ALTO, CA 94304-1050				
EXAMINER				
KISHORE, GOLLAMUDI S				
ART UNIT		PAPER NUMBER		
1612				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/585,705

**Applicant(s)**

TSENG, SCHEFFER C.G.

**Examiner**

GOLLAMUDI S. KISHORE

**Art Unit**

1612

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32, 34, 35 and 39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32, 34, 35 and 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date 7-23-07
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

### **DETAILED ACTION**

Claims included in the prosecution are 1-32, 34-35 and 39.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 23, 32 and 34-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 recites, 'chemical injuries' and 'thermal burn injuries'. It is unclear which tissues are involved in these injuries. The connection between the ocular diseases recited and rosacea which is also recited as the disease is unclear in claim 23.

It is unclear as to what applicant intends to convey by 'urging' or 'urged' in claim 32. Also unclear is what the numbers in parenthesis intend to convey.

Claim 34 does not recite any active agent. Therefore, it is unclear as to what applicant intends to convey by "sustained release of the ointment" in this claim. Entire ointment is released into the eye? What are the components in this ointment?

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 5-8, 13-14, 22-23 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Mausner (5,571,503) of record.

Mausner discloses eye moisturizing compositions containing C13-C14 isoparaffins, mineral oil, squalane, phospholipids, fatty acid esters, cholesteryl behenate, glycerol and medium chain triglycerides (abstract, col. 2, line 45 through col. 7, line 5, col. 9, line 33, Tables and claims).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2, 4, 9-10, 17-26, 28-31, 34-35 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mausner cited above.

As pointed out above, MAUSNER teaches eye compositions containing C13-14 isoparaffins, mineral oil, squalane, phospholipids, fatty acid esters, cholesteryl behenate, glycerol and medium chain triglycerides (col. 2, line 45 through col. 7, line 5, col. 9, line 33, Tables and claims). The amounts of the components in MAUSNER appear to differ from instant amounts. For example, the amounts of phospholipids taught by MAUSNER are up to 1% and not instantly claimed 2 to 10 %. However, in the absence of showing unexpected results it is deemed obvious to one of ordinary skill in the art to vary the amounts of the components of MAUSNER to obtain the best possible results. MAUSNER also does not teach the composition in an ointment form without water.

However, it is

been obvious to one of ordinary skill in the art to prepare a composition in the ointment form if the water soluble components are not necessary. MAUSNER also does not teach instantly claimed mode of administration. In the absence of showing unexpected results, the mode of administration is deemed to be the choice of the artisan.

Furthermore, since transdermal (over the skin) administration of drugs for systemic sustained effect is well known in the art, one of ordinary skill in the art would expect similar results by the application of the composition on the skin over the eyelid.

7. Claims 1-23, 25-32, 34-35 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glonek (5,294,607) in combination with Mausner cited above.

Glonek discloses dry eye treatment compositions. The compositions include phospholipids, triglycerides, cholesterol esters, natural waxes, glycerol, and hydrocarbons. The compositions are administered using injectors and syringes. The composition further includes antibiotics and other medicaments (abstract, col. 8, line 64 through col. 9, line 54, col. 10, lines 28-30, col. 11, lines 22-35 and line 50 through col. 12, line 5).

What is lacking in Glonek is the inclusion of squalane, specific fatty acid esters. Glonek also lacks the teachings of specific triglycerides or hydrocarbons.

The teachings of Mausner have been discussed above. The inclusion of specific fatty acid esters, specific triglycerides and fatty acid esters with a reasonable expectation of success would have been obvious to one of ordinary skill in the art since the reference of Mausner teaches that these compounds are routinely added in eye

moisturizing compositions. The criticality of the specific amounts of each component is unclear to the examiner since the amounts are manipulatable parameters routinely practiced by an artisan. Glonek also does not teach instantly claimed mode of administration. In the absence of showing unexpected results, the mode of administration is deemed to be the choice of the artisan. Furthermore as pointed out above, since transdermal (over the skin) administration of drugs for systemic sustained effect is well known in the art, one of ordinary skill in the art would expect similar results by the application of the composition on the skin over the eyelid.

8. Claims 11, 12, 16, and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mausner or Glonek in view of Mausner as set forth above, further in view of Korb et al (5,371,108) of record.

Mausner does not teach the inclusion of beeswax in the compositions. Glonek teaches the use of natural waxes but does not specify beeswax. Such an inclusion however, would have been obvious to one of ordinary skill in the art since the reference of Korb shows that beeswax is routinely used in combination with hydrocarbon oils for the treatment of dry eye conditions (see abstract, col. 3, lines 15-23, col. 4, lines 6-42, col. 5, lines 7-48 and Examples 45-48).

9. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mausner or Glonek in view of Mausner cited above, further in view of Kaufman (4,923,699) of record.

The teachings of Mausner have been discussed above. What is also lacking in Mausner is the teaching of the inclusion of drugs such as cyclosporin or administration of cyclosporin.

Kaufman while disclosing ophthalmic ointments for dry eye treatment teaches the inclusion of immunosuppressants such as cyclosporin. The compositions further include polar lipid, lecithin and non-polar lipid, cholesterol (abstract, col. 5, lines 33-36, col. 10, lines 60-68, col. 17, line 3 and claim 22). The inclusion of cyclosporin would have been obvious to one of ordinary skill in the art since such an inclusion would provide an immunosuppressant action if needed.

10. Claims 24, 26 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mausner or Glonek in combination with Mausner as set forth above, further in view of Tseng (US 2002/0180929) of record.

The teachings of Mausner and Glonek have been discussed above. What is lacking in these references is the diagnosis of the dry eye condition and analyzing a precorneal lipid film spread before the administration of the composition.

Tseng discloses an apparatus and a method of kinetic analysis of tear interference pattern and lipid film spread. According to Tseng, kinetic analysis of tear interference is useful in devising and monitoring new therapies that are directed to restoring meibomian gland functions (0002-0005; 0009-0011; 0041).

The use of kinetic analysis of tear interference images before the administration of the composition of Mausner and Glonek for the treatment of dry eye conditions would

have been obvious to one of ordinary skill in the art since such a technique is known in the art as taught by Tseng.

11. Claims 25-26, 29-32, 34-35 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mausner or Glonek in combination with Mausner as set forth above, further in view of either Tojo (7,052,714) or Conner (US 2003/0144635) or Araki (US 2003/0203849).

The teachings of Mausner and Glonek have been discussed above. What is lacking in these references is the teaching of the application of the composition to outside skin of an upper eyelid or lower eyelid.

Tojo, Conner and Araki teach that ophthalmic compositions can be applied on the skin of the eyelid (0015-0016 of Conner; 0076 of Araki and col. 7, lines 35-40 of Tojo).

The application of the composition of Mausner or Glonek as claimed would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since the references of Tojo, Conner and Araki each teach that compositions for ophthalmic use can be applied over the skin.

12. Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolle (US 2006/0084684) in view of either Tojo (7,052,714) or Conner (US 2003/0144635) or Araki (US 2003/0203849).

Bolle teaches ophthalmic ointments (abstract; 0001; 0021; 0081). Bolle however, does not specify where the ointment is applied.



Tojo, Conner and Araki teach that ophthalmic compositions can be applied on the skin of the eyelid (0015-0016 of Conner; 0076 of Araki and col. 7, lines 35-40 of Tojo).

The application of the composition of Bolle as claimed would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since the references of Tojo, Conner and Araki each teach that compositions for ophthalmic use can be applied over the skin.

The reference of Penfold (US 2003/0060763) is cited as interest (see figures).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GOLLAMUDI S. KISHORE whose telephone number is (571)272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/  
Primary Examiner, Art Unit 1612

GSK